



NEGATIVE TREND IN ENVIRONMENTAL LABORATORY DATA QUALITY

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Report Documentation Page				Form Approved OMB No. 0704-0188	
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1. REPORT DATE 31 MAR 2011		2. REPORT TYPE		3. DATES COVERED 00-00-2011 to 00-00-2011	
4. TITLE AND SUBTITLE Negative Trend in Environmental Laboratory Data Quality				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S)				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Analytical Quality Associates, Inc, PO Box 21987, Albuquerque, NM, 87154				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION/AVAILABILITY STATEMENT Approved for public release; distribution unlimited					
13. SUPPLEMENTARY NOTES Presented at the 2011 DoD Environmental Monitoring & Data Quality Workshop (EMDQ 2011), 28 Mar ? 1 Apr, Arlington, VA. U.S. Government or Federal Rights License					
14. ABSTRACT					
15. SUBJECT TERMS					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT Same as Report (SAR)	18. NUMBER OF PAGES 20	19a. NAME OF RESPONSIBLE PERSON
a. REPORT unclassified	b. ABSTRACT unclassified	c. THIS PAGE unclassified			



Background

- Validating environmental data for 11 years
- Nationwide client base
 - Government agencies
 - Native American tribal governments
 - Environmental engineering firms

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AQA Validates Data from Numerous Laboratories

- From small labs to the largest environmental laboratories
- We have observed a general and substantial decline in data quality
- “QC only” DV, manual or automated, will not detect most of the deficiencies
- These deficiencies are often detrimental to data accuracy and defensibility

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Examples

***(We didn't have too look hard
to find these)***

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Falsification of Instrument Calibration

- Laboratory manually changed the standard areas
- Years of data affected on high-profile government project
- This problem was found by manually calculating the curve statistics from raw data
- Would not have been caught by automated data review or “QC only” data validation

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A green line graph showing a single, sharp, symmetrical peak, typical of a chromatogram, positioned on the right side of the slide.



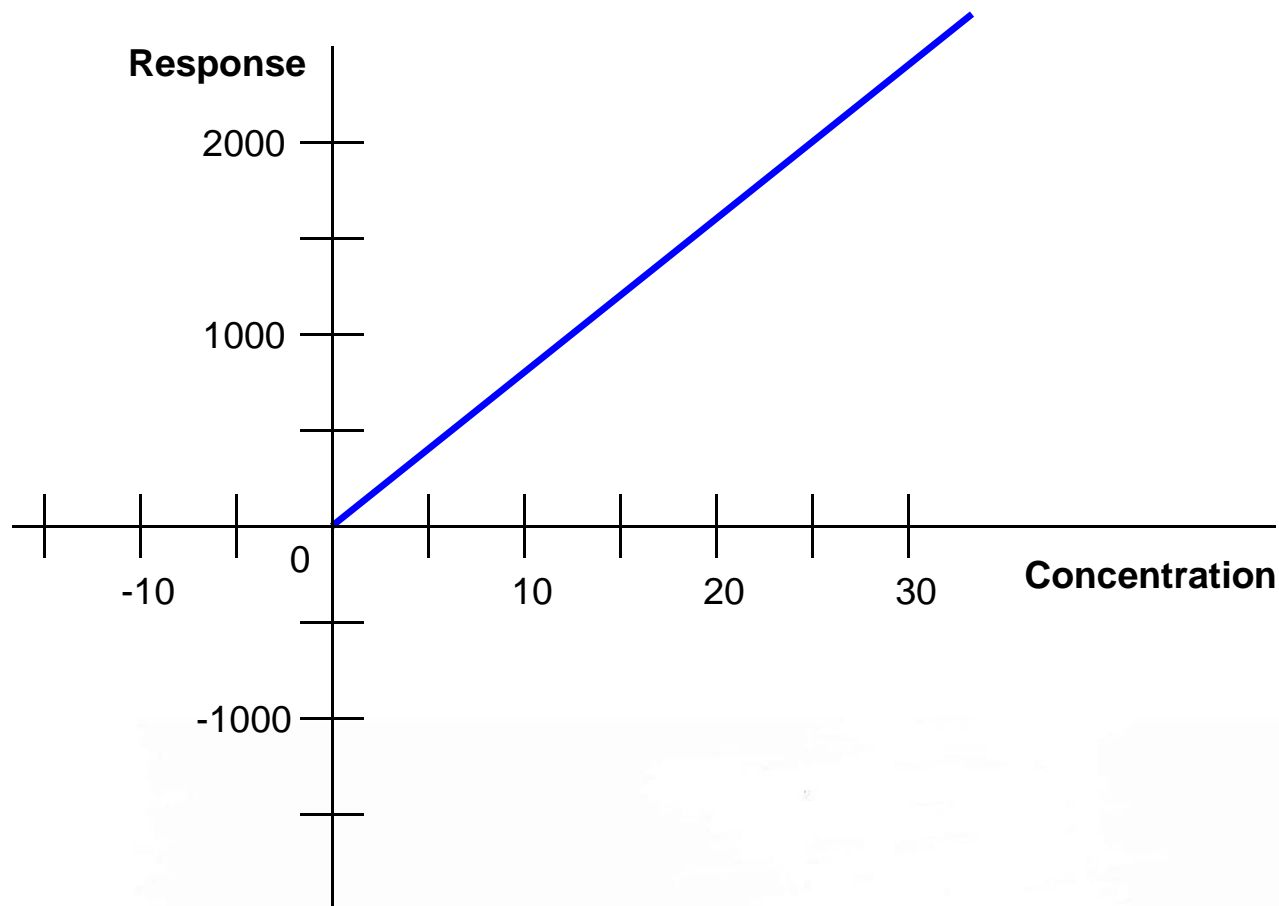
Response to Average RF CAL Failure: Hide Behind a Poor Linear Fit

- Average RF calibration failed
- Resort to a linear fit (non-weighted)
- Coefficient of determination (r^2) passed
- However, concentration-intercept was unacceptably different from zero and negative (see next slide)
- Both positive and negative intercept situations often observed. Labs only look at r^2 value and not the intercept.

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Small Concentrations Missed / Higher Concentrations Biased Low



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Prohibited Removal of Calibration Points

- Removal of interior calibration points for acetone
- Direct violation of EPA Method 8000
- Direct violation of laboratory SOPs and ethics agreements
- All results acquired against this curve are grossly indefensible

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97% Failure Rate for MS/MSD Analyses

- Method 8151
- Laboratory claimed they had adequate cleanup (GPC) capabilities
- No GPC existed
- No confidence in the reliability of the data

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Analyzing QC on a Separate Instrument

- Defeats the several key goals of QC. For example, MB analysis will indicate contamination of prep and instrument. LCS is used to measure control of entire analytical process, not just extraction.
- Laboratory returned to same practice after being notified it was not acceptable
- Whether a time-saver or malicious, severely hampers defensibility of data.
- Dramatically increases data validation labor and costs

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Some Other Examples

- Unreported positive hits
- Misreported QC recoveries
- Multiple manual integrations to make QC pass
- Misused/overused “matrix effects” assertions
- Failure to perform required re-analyses
- Rampant QC/IS/surrogate failures
- Failure to maintain certifications
- Failure to perform blank population MDCs

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What's Causing This Decline?

**Largely Attributable to Lowest Price — Technically
Acceptable (LPTA) Contracting**

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Problems with LPTA

- Failure to adequately determine Technical Acceptance
- Deviation from Best Value approach to contracting
- Price becomes only concern, there is a perfunctory nod to actual quality, not a real inquiry

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Effects of LPTA on Laboratory Operations (1)

- You are not the lowest bidder, you lose!
- You must trim laboratory operations so you can be the low bidder

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Effects of LPTA on Laboratory Operations (2)

- Increased laboratory burden
 - Decreased per sample price / increased number of samples to generate same revenue
 - Analytical shortcuts
- Eroded management commitment to quality
- Decreased quality assurance oversight
- Deliverable corrections and CAR responses not delivered in a timely manner

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What is Technically Acceptable?

- Laboratory scope and capacity
- Proper equipment
- Qualified personnel
- Quality systems
- Reporting capability
- Track record of compliant on-time performance

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How is Technical Acceptability Typically Verified?

- Review of laboratory proposals only
(no pre-qualification audit)
- Pre-qualification audits by QA officers only
- Sending technical staff who are not experienced analytical chemists
- Reliable verification is accomplished via a pre-qualification audit performed by experienced analytical chemist(s)

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Common Misconceptions

- Laboratory certifications guarantee a technically qualified lab
 - Implementation of a standard is only as good as the personnel implementing it
 - AQA has observed serious failures by certified laboratories
- Information supplied by laboratories is comprehensive and accurate
 - Laboratory assertions are often misleading at best

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Consequences of Inadequate Verification

- Acquisition of indefensible data
- Misleading data such as false positives or false negatives
- Diminished quality (excessive qualification)
- Contracts awarded to laboratories that do not have sufficient capacity to generate compliant data on-time

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Summary

- Overall decline in environmental laboratory data quality
- LPTA contracting, to a substantial degree, is a root cause of the declining quality
- Meaningful technical acceptability verification needed
- Problems presented are the tip of the iceberg
- Problems won't be found using automated data validation software or cursory "QC Only" data validation

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